Insufficient Scientific Evidence for Prometa

By Richard Rawson, PhD and A. Thomas McLellan, PhD

When asked at a House Subcommittee hearing (June 28, 2006) if she supported use of the Prometa Protocol, **Nora Volkow, MD** Director of NIDA, said "…it has become extraordinarily important for us to provide objective evidence of the effectiveness of treatment interventions…. to my knowledge, and I've looked into the literature, there is no randomized study that has proven the effectiveness of Prometa…." She noted that pilot studies showing positive results (offered as evidence by Hythiam) are open trials in which "the placebo effect is likely to compound the results…. Do I support the utilization of treatments that are not evidence-based? No, I do not." The response of Dr. Volkow recommending against the use of procedures without evidence of scientific support directly applies to Prometa.

While not perfect, the approval process for new medications, medical interventions and medical devices under the direction of the Food and Drug Administration (FDA) is the most thorough in the world. There are comparatively few health problems from medications, medical devices or medical interventions that have received approval by the FDA. This is because the agency has developed and employed a very long and rigorous five-stage process of testing for safety and efficacy involving animal testing, clinical laboratory tests, clinical efficacy and effectiveness testing and finally post marketing testing for rare complications.

The studies conducted on new medications involve thousands of volunteer research participants who receive the medication or medical intervention under "double-blind, placebo controlled conditions." This means that under this type of testing neither the participant nor the doctor administering the drug are aware of whether the drug being administered is the actual medication or a placebo. Thus, when a new medication or device or intervention shows the ability to relieve symptoms or improve function under these conditions it is safe to conclude that it is a true effect, not caused by experimenter or patient bias – since all parties are "blind" to what was actually being administered. These "double-blind, placebo controlled studies are essential to prove both the safety and efficacy of a new medication.

While buprenorphine, naltrexone and acamprosate have undergone this FDA approval process, a number of experimental medical procedures or "protocols" (e.g., "ultra-rapid opiate detoxification, or "UROD" and Prometa) have also appeared via billboard and other media advertising campaigns as new scientific breakthroughs for the treatment of substance use disorders. Because these procedures or protocols do not involve new medications or medical interventions, just procedures or combination of drugs that have been approved for uses other than addiction, these procedures have not been required to undergo full testing by the FDA or any other monitoring authority.

These proprietary procedures may ultimately be shown to be effective someday following full testing. However, claims of effectiveness not substantiated with FDA-style testing results are inconclusive at best, misleading at worst. At present, none of the Prometa "studies" cited on the Hythiam website has any form of comparison or control group. Open trials are highly susceptible to placebo effects.

As decisions are made by policy makers to pay for new treatments with taxpayer dollars, it is important to understand whether the new "treatments" have completed an adequate process of evaluation. Given that there are already approved medications and other interventions that have passed full testing, it may be considered inadvisable to allow public reimbursement for experimental procedures which have not been proven safe, or effective. It would be unfortunate if the limited public funds available for substance abuse treatment were to be squandered on untested experimental techniques which ultimately prove to be unsafe or ineffective. Before approving new addiction "treatments" for reimbursement with taxpayer dollars, those in policy making positions should become knowledgeable about the nature of the evidence to support these new medications/procedures.

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In this regard, Dr. Volkow's verbatim testimony is important:

In the field of drug addiction, it has been very, very difficult to change the culture to accept drug addiction as a disease and as you know, we are treated differently in that private insurances do not cover the treatment. Why? Because they say drug addiction treatment does not work.

And so it has become extraordinarily important for us to provide objective evidence of the effectiveness of treatment interventions. And it is harmful to the field to promote any treatment without that evidence, because it serves to… propagate the sense that treatment does not work. ▪

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